U.S. DEPARTMENT OF COMMERCE
National Technical Information Service

PB-270 978

Management Policy for the Assurance of Research Quality, Health Effects Research Laboratory Research Triangle Park, North Carolina

Health Effects Research Lab, Research Triangle Park, N.C.

Jun 77

EPA-600/1-77-036
June 1977

PB 270 978

Environmental Health Effects Research Series

MANAGEMENT POLICY FOR THE ASSURANCE OF PRODUCT QUALITY: CASE STUDIES BEHAVIOR LABORATORY, RTP, NC

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

TECHNICAL REPORT DATA

(Please read Instructions on the reverse before completing)

1 REPORT NO. EPA-600/1-77-036	2
3 RECIPIENT'S ACCESSION NO.	
4 TITLE AND SUBTITLE: Management Policy for the Assurance of Research Quality - Health Effects Research Laboratory/RTP, NC	5 REPORT DATE June 1977
	6 PERFORMING ORGANIZATION CODE
7 AUTHOR(S):	8 PERFORMING ORGANIZATION REPORT NO.
9 PERFORMING ORGANIZATION NAME AND ADDRESS: U.S. Environmental Protection Agency, Office of Research and Development, Criteria and Special Studies Office, HERL, Research Triangle Park, NC 27711	10 PROGRAM ELEMENT NO. 1AA601
	11 CONTRACT/GRANT NO.
12 SPONSORING AGENCY NAME AND ADDRESS: Health Effects Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711 RTP,NC	13 TYPE OF REPORT AND PERIOD COVERED
	14 SPONSORING AGENCY CODE EPA 600/11

15 SUPPLEMENTARY NOTES

16 ABSTRACT

This document presents policies, goals, and an organizational structure for the implementation of a management policy for the Quality Assurance program in the Health Effects Research Laboratory, Research Triangle Park, North Carolina. Directed toward functional managers, a system for quality assurance monitoring of task quality control functions is described.

General areas affecting data quality are discussed from the perspective of the manager as a reviewer of documents or plans. The quality assurance organization, consisting of a Quality Assurance Coordinator and a Quality Assurance Committee, serves in an advisory capacity to taskmasters as well as to regular functional management. Within this structure, the application of quality assurance measures is the responsibility of taskmasters or project officers. It is the responsibility of functional management to ensure that all project-oriented documents or plans have incorporated appropriate quality assurance procedures.

17 KEY WORDS AND DOCUMENT ANALYSIS

17a DESCRIPTORS	17b IDENTIFIERS/OPEN ENDED TERMS	17c COSATI Field/Group
Quality Assurance Management Research Projects Health Quality Quality control	Health Effects Laboratory Quality Assurance	05 A 14 B

18 DISTRIBUTION STATEMENT	19 SECURITY CLASS (This Report) Unclassified	21 NO. OF PAGES 75
	20 SECURITY CLASS (This Page) Unclassified	22 PRICE $3.25 PC

EPA Form 2220-1 (9-73)

RESEARCH REPORTING SERIES

Research reports of the Office of Research and Development, U.S. Environmental Protection Agency, have been grouped into nine series. These nine broad categories were established to facilitate further development and application of environmental technology. Elimination of traditional grouping was consciously planned to foster technology transfer and a maximum interface in related fields. The nine series are:

1. Environmental Health Effects Research
2. Environmental Protection Technology
3. Ecological Research
4. Environmental Monitoring
5. Socioeconomic Environmental Studies
6. Scientific and Technical Assessment Reports (STAR)
7. Interagency Energy-Environment Research and Development
8. "Special" Reports
9. Miscellaneous Reports

This report has been assigned to the ENVIRONMENTAL HEALTH EFFECTS RESEARCH series. This series describes projects and studies relating to the tolerances of man for unhealthful substances or conditions. This work is generally assessed from a medical viewpoint, including physiological or psychological studies. In addition to toxicology and other medical specialities, study areas include biomedical instrumentation and health research techniques utilizing animals — but always with intended application to human health measures.

This document is available to the public through the National Technical Information Service, Springfield, Virginia 22161.

EPA-600/1-77-036
June 1977

MANAGEMENT POLICY FOR THE ASSURANCE OF RESEARCH QUALITY HEALTH EFFECTS RESEARCH LABORATORY RESEARCH TRIANGLE PARK, NORTH CAROLINA

Quality Assurance Document #1

This Manual Valid Through Fiscal Year 1978

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT
HEALTH EFFECTS RESEARCH LABORATORY
RESEARCH TRIANGLE PARK, N.C. 27711

DISCLAIMER

This report has been reviewed by the Health Effects Research Laboratory, U.S. Environmental Protection Agency, and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

FOREWORD

The U.S. Environmental Protection Agency's Health Effects Research Laboratory located at Research Triangle Park, North Carolina conducts an extensive research program to evaluate the human health implications of environmental factors related to industrialized society. The purpose of this research is to provide information necessary to formulate environmental regulatory policies to protect or improve public health and welfare while at the same time enhancing the nation's productivity. To this end, the Laboratory conducts a comprehensive program in toxicology, epidemiology, and research on human subjects under controlled laboratory conditions. The quality of the data resulting from this research is an overriding factor in determining the usefulness of this information in EPA's regulatory activities. In recognition of the importance of data quality assurance, our Laboratory has initiated a comprehensive program to coordinate all the current activities in this area. Accordingly, the policies enunciated in this document become effective immediately upon publication and will remain in effect until revisions are announced. In order to assist scientists in our Laboratory in the preparation of research protocols that include the best elements of data quality assurance, a guidelines manual will be published shortly after the appearance of this policy document. I am confident that full implementation of our data quality assurance policy with the help of the guidelines manual and the increased awareness of the importance of good data acquisition and management procedures will enhance the scientific merit of our research program.

John H. Knelson, M.D.
Director,
Health Effects Research Laboratory

ACKNOWLEDGEMENTS

Following considerations from many program managers within the Health Effects Research Laboratory, this document was completed through the work of the Quality Assurance Committee, HERL-RTP, whose members reviewed and criticized the manuscript and made many helpful suggestions.

HERL Quality Assurance Committee
1977-78

Ferris Benson - Criteria and Special Studies Office
Robert Burton - Population Studies Division
Dorothy Calaflore - Population Studies Division
Walter Crider - Clinical Studies Division
George Goldstein - Clinical Studies Division
Ralph Linder - Environmental Toxicology Division
Margarita Morrison - Program Operations Office
Gerald Mehlo - Statistics and Data Management Office
Edward Oswald - Environmental Toxicology Division
Georgia Rehnberg - Experimental Biology Division
Ralph Smialowicz - Experimental Biology Division
David Svendegaard - Statistics and Data Management Office

CONTENTS

		Page
1.0	SUMMARY	1
2.0	INTRODUCTION	2
2.1	Document Organisation	2
2.2	Definitions	2
2.2.1	Quality	2
2.2.2	Quality Assurance (QA)	3
2.2.3	Data Quality Control (DQC)	3
2.2.4	Data Quality Assurance (DQA)	4
2.2.5	Task	4
2.2.6	Protocol	4
2.3	Laboratory Mission	4
2.4	Data Quality at HERL-RTP	5
3.0	QUALITY GOALS	6
3.1	General Goal	6
3.2	Specific Goals	6
4.0	QUALITY POLICIES	8
4.1	Coverage of the Quality Assurance Program	8
4.2	Responsibility for Application of Quality Procedures	9
4.2.1	Quality Control	9
4.2.2	Quality Assurance	9
4.3	Scope of Quality Assurance Program	9
5.0	QUALITY ASSURANCE PROGRAM ORGANIZATIONS	14
5.1	Organizational Structure	14
5.2	Functional Responsibilities	16
5.2.1	Accomplishment Plan Manager	16
5.2.2	Task Management	18
5.2.3	Functional Management	18
5.2.4	Quality Assurance Coordinator	19
5.2.5	Quality Assurance Representative	21
5.2.6	Quality Assurance Committee	22
6.0	REFERENCES	23
7.0	BIBLIOGRAPHY	23

FIGURES

Number		Page
1	Example of major topics addressed in a task protocol	11
2	Example of required task protocol approvals.	12
3	Summary of essential aspects of technical data quality . . .	13
4	HERL-RTP's functional management structure	15
5	Quality assurance program structure within HERL-RTP.	17
6	Quality assurance coordinator's communication links with QA expertise outside of HERL-RTP	20

1. SUMMARY

This document presents policies, goals, and an organizational structure for implementation of a management policy for quality assurance (QA) in the Health Effects Research Laboratory, Research Triangle Park (HERL-RTP). Directed toward functional managers, a system for QA monitoring of task quality control functions is described. Following delineation of HERL-RTP quality policy and goals, the organizational structure for the Quality Assurance Program and its relationship to functional management responsibilities are discussed.

The QA organization, consisting of a Quality Assurance Coordinator and a Quality Assurance Committee, serves in advisory capacity to regular functional management. Application of QA measures is the direct responsibility of taskmasters or project officers. It is the responsibility of functional management to insure that any project-oriented document or plan has incorporated appropriate QA measures and has been reviewed and approved through management channels.

This document, delineating management policies for quality assurance, is the first in a series of HERL-RTP quality assurance guidelines which will be incorporated into the HERL-RTP quality assurance policy manual. A companion document directed toward taskmasters should be available by September 1977. Areas requiring specific guidelines development are presently being identified.

The respective sections of this document are directed toward the various management functions as follows:

Section	1.	2.	3.			4.			5.					
Subsections			3.1	3.2	3.3	4.1	4.2	5.1	5.2					
									5.2.1	5.2.3	5.2.3	5.2.4	5.2.5	5.2.6
APPLICABLE TO:														
Accomplishment Plan Managers	✓	✓	✓	...	...	✓	...	✓	✓	...	...	...	...	...
Taskmasters	✓	✓	✓	✓	✓	✓	✓	✓	...	✓	...	...	...	...
Functional Managers	✓	✓	✓	✓	✓	✓	✓	✓	...	...	✓	...	...	...
QA Coordinator	✓	✓	✓	✓	✓	✓	✓	✓	...	...	...	✓	...	...
QA Representatives	✓	✓	✓	✓	✓	✓	✓	✓	...	...	...	...	✓	✓

2. INTRODUCTION

2.1 DOCUMENT ORGANIZATION

The succeeding sections of this document present the HERL-RTP quality assurance (QA) management policy, and are organized as follows:

Section 3 lists general and specific goals of the HERL-RTP quality assurance program.

Section 4 contains a discussion of the general features of the HERL-RTP quality assurance program. Following a description of the coverage of the program, the taskmasters' responsibilities for quality assurance are outlined. The section ends with a brief discussion of the program and a list of QA elements of importance to health-related research.

Section 5 delineates the organization for implementing the HERL-RTP quality assurance program. Present management positions and their roles in the QA program are first discussed, followed by a detailed description of the integrated QA organization specifically relating to the functioning of the program.

2.2 DEFINITIONS

It is useful to define six terms which will appear frequently in this document: (data) quality, quality assurance (program or plan), data quality control (DQC), data quality assurance (DQA), task, and protocol. (1, 2)

2.2.1 Quality

Quality means the totality of features and characteristics of a product or service that bear on its ability to satisfy a previously specified need. For measurement systems, the product is measurement data, and the characteristics of major importance are accuracy, precision, and representativeness. For monitoring systems, completeness--or the amount of valid measurements obtained relative to the amount expected to have been obtained--is an additional important measure of quality.

2.2.2 Quality Assurance

Quality assurance is the term used to describe a comprehensive system of plans, specifications, and policies which are designed to insure the collection, processing, and reporting of quality data in a cost-effective manner. Thus, a QA plan for a particular task, or a QA policy for a laboratory (e.g., HERL-RTP) may properly be discussed. Quality assurance provides for total system data quality, resulting from data quality control and data quality assurance--from experimental design (e.g., sensor positioning) through final report production (e.g., confidence limits and limits of applicability of results). In addition, it addresses possible needs for methods development and independent value judgments of the relevance of a proposed technical task to prior specified HERL-RTP or EPA needs.

Responsible research laboratories are regularly involved with various aspects of data quality verification as part of good laboratory practice. A comprehensively defined QA plan, as will be described in this document, serves several additional functions. First, it outlines the steps of the program and therefore can be used to explain concisely what the program involves. Second, it provides a means for independently assessing and documenting data quality; and third, it provides a mechanism for evaluating the relevance of a (proposed) task to laboratory and agency goals.

Maintaining the HERL-RTP quality assurance program is the function of taskmasters and managers, with assistance from the HERL-RTP Quality Assurance Coordinator.

2.2.3 Data Quality Control (DQC)

Data quality control is a system of activities designed to achieve and maintain a previously specified level of quality in data collection, processing, and reporting. DQC is performed by the organization actually carrying out the task or project; i.e., it is executed by task personnel. As discussed in section 4.3, DQC activities include control of or correction for all variables suspected of affecting data quality. These variables include instrument maintenance and calibration; quality of reagents and supplies; technical personnel qualifications; animal care and handling (where applicable); environmental parameters; and others.

2.2.4 Data Quality Assurance (DQA)

Data quality assurance is a system of activities designed to provide management with an independent assurance that total system data quality control is being performed effectively. DQA activities are both qualitative and quantitative. To perform qualitative reviews, DQA personnel will visit sites to conduct systems reviews. A variety of techniques are available for quantitative review. Blind samples, collaborative testing, and round-robin analyses are some of the usual techniques used to quantitatively verify DQC effectiveness. These and other, as yet undeveloped DQA techniques will be applied to the health-related research performed in the HERL-RTP.

2.2.5 Task

A task is an in-house or contracted project, or interagency agreement, the purpose of which is to produce technical research data for the HERL-RTP program.

2.2.6 Protocol

As used in this document, the term protocol should be understood to include all task or project planning documents used at the HERL-RTP. Specifically included are task protocols, procedure statements, work plans, and scopes-of-work, irrespective of the nature of the task or organization actually performing the task.

2.3 LABORATORY MISSION

The Health Effects Research Laboratory, Research Triangle Park, conducts animal and human studies under controlled conditions and performs additional studies on human populations in order to assess the hazard to human health of exposure to environmental pollutants. Laboratory scientists determine the effects of environmental pollutants both alone and in combination; pollutant types that are studied include air pollutants, pesticides, toxic substances, and nonionizing radiation. Controlled laboratory studies are devoted to determining effects of pollutants on normal biological function as measured by clinical, chemical, biochemical, physiologic, histopathologic, growth, reproduction, and other parameters.

HERL-RTP also develops, evaluates, and improves analytical chemical methods and biological screening techniques for direct and indirect measurement of exposure to environmental toxicants. It also serves as a resource for information on health effects of environmental pollutants and coordinates health-related activities with international organizations.

2.6 DATA QUALITY AT HERL-RTP

HERL-RTP has long recognized the importance of quality control in its research activities. For example, pesticide QA programs have been supported for several years and have been of service to well over 100 laboratories. In addition to the pesticide analytical procedures, several related QA manuals have been prepared under this program. Interlaboratory pesticide QA programs have also been maintained for several years.

However, quality control has generally been practiced on a project-by-project basis, with the preparation and implementation of a quality control plan being the responsibility of individual taskmasters. Due to increased awareness of the deleterious effects of pollutants on living systems, HERL-RTP has recognized the need for a formal, comprehensive, laboratorywide data quality program.

A formal HERL-RTP data quality program was initiated in May 1976 with the issuance of a "Quality Assurance Plan" by HERL-RTP (3). Subsequent actions include the appointment of a Quality Assurance Coordinator (QAC) and a Quality Assurance Committee for the purpose of designing and implementing a QA program appropriate to the unique requirements of the HERL-RTP. While specific quality assurance guidelines have been developed for ambient air measurements, lack of adequate guidelines for quality assurance in biological research has hampered the completion of an integrated program at the HERL-RTP.

3. QUALITY GOALS

3.1 GENERAL GOAL

The goal of the HERL-RTP Laboratory Quality Assurance Program is to insure, assess, and document the medical and scientific reliability of laboratory and field data used in EPA's activities and documents relating to human health. Management, administrative, statistical, investigative, preventive, and corrective techniques will be employed to maximize reliability of the data.

3.2 SPECIFIC GOALS

The specific goals are to:

a. Provide a vehicle which will alert all personnel within HERL-RTP to the basic concepts of quality control (QC) and quality assurance (QA), and to the level of quality expected within HERL-RTP. In particular, the program should cultivate in each person a consciousness of quality in daily work, and should enhance their ability to recognize areas deficient in quality assurance and to take corrective action.

b. Establish and maintain guidelines to assist HERL-RTP personnel in the logical development of general and specific quality assurance directives for current and future HERL-RTP analysis and testing processes, which include in-house and contracted tasks.

c. Present and maintain current an organization plan for HERL-RTP management and administration which defines QA functions and responsibilities of personnel and establishes lines of communication necessary to achieve QA goals.

d. Provide a means for evaluating task TPP's, protocols, or procedures statements for appropriateness to the current and anticipated data requirements of HERL-RTP.

e. Use (and as necessary, develop) methods of analysis and data treatment which are capable of meeting both (1) the needs of precision, accuracy, sensitivity, and specificity demanded by HERL-RTP guidelines, and (2) the use for which the data are intended.

f. Maintain awareness of new and/or improved methods of analysis and data interpretation, and implement any needed changes in routine and analytical measurements to achieve QA standards.

g. Monitor the routine operational performance of HERL-RTP through appropriate intralaboratory and interlaboratory programs and corrective action provisions.

h. Participate in quality evaluation programs while data are being collected, through coordination with: evaluation services provided by other laboratories of ERC-RTP; other EPA laboratories; other government agencies (NIOSH, OSHA, NBS); and private contractors.

i. Insure that EPA contractors develop approved QA plans and procedures (prior to contract work) and adhere to them in all stages of the contracted work.

j. Implement, as part of the management plan, a procedure to review QA aspects of research protocol and data currently being collected, or data collected in the past, as deemed appropriate.

k. Identify problem areas, alert management to them, and correct the problems; also, validate the soundness of the solution to each problem.

4. QUALITY POLICIES

HERL-RTP policies pertaining to the development, implementation, and maintenance of a quality assurance (QA) program are described by category below.

4.1 COVERAGE OF THE QUALITY ASSURANCE PROGRAM

The HERL-RTP quality assurance program is complete in concept, encompassing all technical tasks, and it is strongly recommended that it also include grants. All technical tasks, both in-house and contractual, must have a research protocol quality control plan delineating the practices and procedures to be followed at each level (e.g., technician, bench chemist, project leader) and each phase in the life of the project. The QA program also requires that each task contain a quality assurance plan for independently monitoring the effectiveness of that task's quality control program. The administrative responsibility for evaluation and approval of quality control and quality assurance aspects of the HERL-RTP quality assurance program is assigned to the Quality Assurance Coordinator. The QA program will be applied on a project-by-project basis according to the project objectives and requirements. Responsibility for design and implementation of the project QA plan rests with the respective taskmaster and functional management.

As indicated above, the taskmaster is responsible for the design of a QA plan suitable for a particular task, subject to functional management review and approval. In this way, specific QA activities can be chosen that are appropriate to the data quality requirements of the task and also to the nature of the data collection and processing systems. For instance, repetitive measurement operations require QA activities significantly different than those for measurement methods under development. Taskmasters should be aware that truly unique measurement methods are used quite rarely; well-characterized methods are the norm, even for tasks which are strongly "research" oriented. Therefore, a QA plan may necessarily focus on specific components of the data system for some tasks rather than on the system as a whole.

4.2 RESPONSIBILITY FOR APPLICATION OF QUALITY PROCEDURES

Data quality practices and procedures take two forms: data quality control and data quality assurance. Responsibility for each is described in this section.

4.2.1 Quality Control

The taskmaster must insure that data quality is sufficient to meet project requirements; it is therefore up to this person to design and insure adherence to procedures that will guarantee such data quality. For example, on tasks conducted under contract (see section 4.3), the DQA plan is prepared by the contractor and reviewed and approved by the EPA project officer with optional assistance from the Quality Assurance Coordinator. In-house tasks have DQA plans incorporated in the research protocol by the responsible taskmaster, with optional assistance from the Quality Assurance Coordinator.

4.2.2 Quality Assurance

The HERL-RTP Quality Assurance Coordinator, with assistance from the Quality Assurance Committee, establishes and administers data quality assurance procedures for independently monitoring and assessing the efficiency and adequacy of individual quality control programs. The DQA procedures shall be applied uniformly throughout the duration of the project. However, at any time during the task life, either the subject taskmaster or the Quality Assurance Coordinator, using accepted QA techniques, may assess the HERL-RTP project's ongoing data quality control program as deemed necessary.

4.3 SCOPE OF QUALITY ASSURANCE PROGRAM

The data quality assurance program for extramural (contracted) projects provides for data quality control procedures applied to the request for proposal (RFP), the proposal, and extending through proposal evaluation, workplan approval, project and quality control execution, and final report preparation. It also provides for appropriate data quality audits.

In the case of intramural (in-house) projects, data quality control procedures begin with the drafting of the protocol (see section 2.2.6).

in particular, consideration of the hypothesis to be tested, data and data processing requirements, data quality assurance plans and procedures, data analysis techniques, and anticipated problem areas should be clearly addressed. (See figures 1 and 2 for a description of typical points of a task protocol and required approvals, respectively.) Protocol review and approval will include evaluation of QA plans.

Planning for technical tasks should include provision for an appropriate QA program. This program will be comprised of both DQC plans and DQA plans. The following aspects of data quality should be addressed:

a. organizational structure as it relates to data quality;

b. sample collection and analysis procedures (including such items as questionnaire design, animal integrity, tests and controls, etc.);

c. calibration standards and procedures;

d. the validity and applicability of the experimental procedures (to be) used, including sources of potential error. Assuring appropriate experimental statistical design is involved here;

e. the validity and applicability of experimental variables affecting data quality. These include procurement, acceptance, and storage of consumables (reagents, animals, etc.) and nonconsumables (instrumentation, relevant laboratory design, etc.); data processing; and statistical analysis;

f. plans for corrective action when data of unacceptably poor quality are encountered;

g. statistical data analysis and report preparation, with estimates of confidence limits on the data; a statement of the estimated limits of applicability of the results;

h. personnel technical and professional qualifications as related to their assigned responsibilities.

A summary of these essential aspects of technical data quality is presented in figure 3.

- Providing a clear statement of the hypotheses to be tested.
- Considering generally how results are to be demonstrated, particularly graphical presentations of data.
- Proposing analyses of:
  a. covariables (or covariates) considered
  b. other possibly important covariables
  c. controls to be used.
- Considering what data are needed to undertake this analysis and how they are to be processed.
- Considering what quality assurance plans and procedures will be implemented. If comprehensively treated in other sections of the protocol, they should be referenced. Also see section 4.3.
- Determining whether new or old collection forms are needed.
- Determining the number and kinds of study subjects needed, and the statistical basis for the choice.
- Deciding upon a schedule for testing and other data collection (this includes scheduling the obtaining of exposure data and collection in particular areas when appropriate). Also, deciding upon the statistical basis for the sampling schedule and the number of sampling sites.
- Determining how to initiate the study and when subject selection and data collection are to begin.
- Determining the time span necessary for data collection and when data will be available for analysis.
- Determining the duration needed for data analysis: are analysis programs on hand?
- Deciding when draft reports and final report will be completed.
- Estimating anticipated problem areas in carrying out the study.

(Details of the elements of QA will be developed in document #3.)

Figure 1. Example of major topics addressed in a task protocol.

Submitted by: _____
Name

Approvals: _____ _____
Section Chief Branch Chief

_____ _____
Statistical Consultant Division Director

_____ _____
AP Manager Laboratory Director

Figure 2. Example of required task protocol approvals.

a. ORGANIZATIONAL STRUCTURE FOR DATA QUALITY

b. SAMPLE COLLECTION

c. CALIBRATION

d. EXPERIMENTAL PROCEDURES

e. VARIABLES WHICH CAN AFFECT DATA QUALITY

f. PLANS FOR CORRECTIVE ACTION

g. DATA ANALYSIS

h. PERSONNEL QUALIFICATIONS

(See section 4.3 for details.)

Figure 3. Summary of essential aspects of technical data quality.

5. QUALITY ASSURANCE PROGRAM ORGANIZATION

Within the existing management structure in the Health Effects Research Laboratory, Research Triangle Park, a simple but efficient quality assurance (QA) substructure is intermeshed. The organization of the substructure, the functional responsibilities of QA personnel and other EPA personnel involved in the Quality Assurance Program implementation, and the lines of internal and external communication for the achievement of a cost-effective program are discussed in this section.

The Quality Assurance Coordinator (QAC) will be appointed by the Laboratory Director. Representatives to the QA Committee will be appointed by the respective Division or Office manager. Alternate representatives will also be appointed by the respective Division or Office manager to serve in the absence of that Division's representative. Considerations in the choice of the alternate should include the possibility of representative-alternate communication (if both are chosen from the same branch or section) as well as the potential for broader based representation (if the representative and alternate are from different disciplines).

5.1 ORGANIZATIONAL STRUCTURE

The HERL-RTP functional management structure is shown in figure 4. As mentioned in the previous sections of this manual, the Quality Assurance Program will encourage an awareness and usage of quality assurance principles at every level of functional and task management. Primarily responsible for the design and implementation of the program is the Quality Assurance Coordinator, who reports on QA matters directly to the HERL-RTP Director. An advisory committee chaired by the QAC is comprised of QA representatives from each Division and Office. This committee, the Quality Assurance Committee, is responsible for analyzing the efficiency of the program across the Laboratory and for recommending viable improvements. The quality assurance representatives, in addition to serving as members of the QA Committee, act as liaisons between the QA Committee (and/or the QAC) and their respective Divisions or Offices.

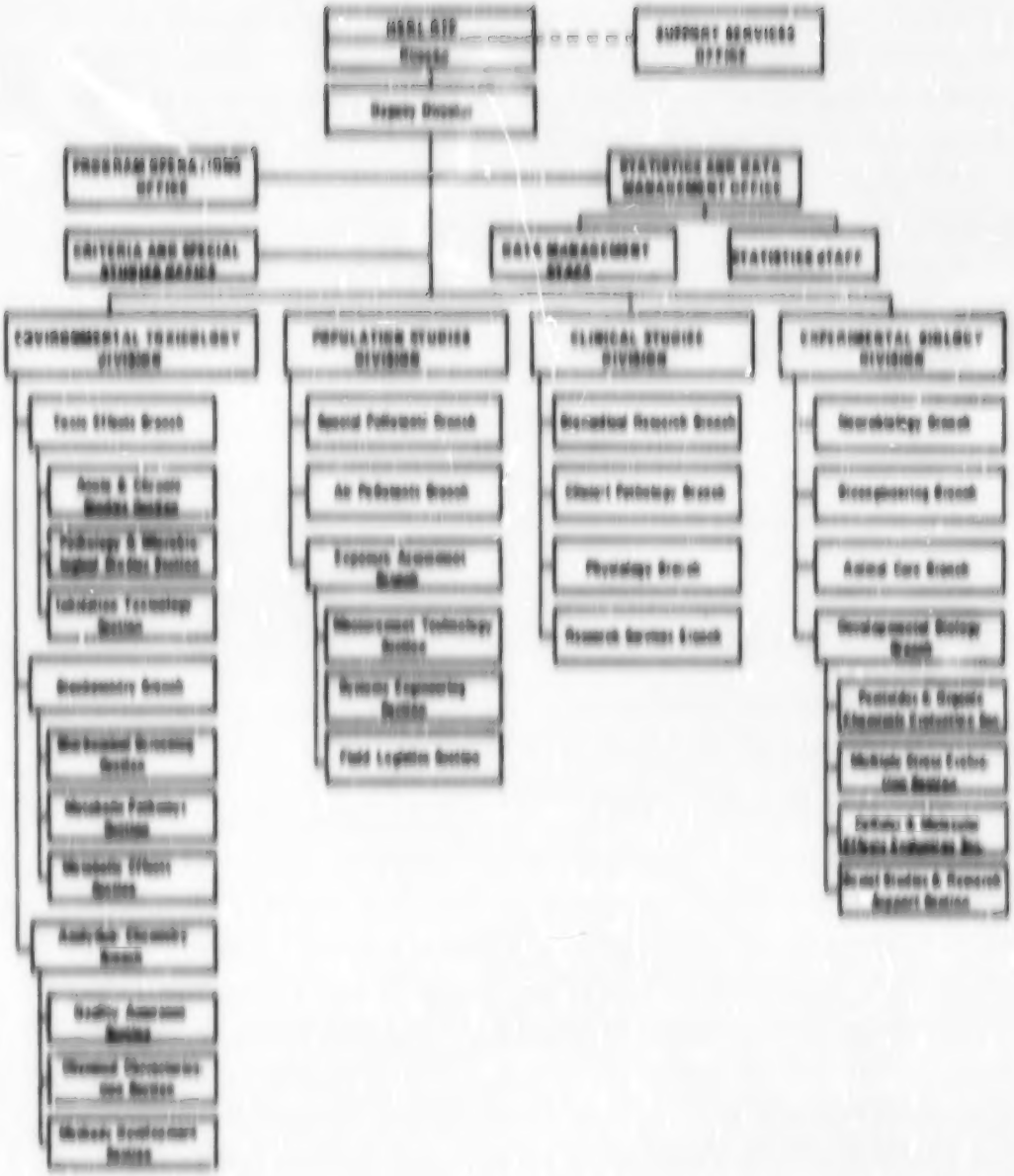

Figure 4. HERL-RTP's functional management structure.

The actual incorporation of quality control procedures into individual projects is the responsibility of each project's officer or taskmaster. Beginning with the concept paper or request for proposal, all documents which contain a description of the technical or analytical aspects of the project must be accompanied by a description of the quality control requirements and how they will be met. Hence, in the standard review and approval process of any project-oriented document (e.g., SPF, proposal, workplan, etc.), the DQC plan must be reviewed and approved along with the other technical or analytical aspects of the work. DQA methodologies must also be contained in the scope of the project and described in the project documents. The Quality Assurance Coordinator or a designee may work with the taskmaster/project officer to design or refine the DQA procedures to meet the program requirements outlined in this quality assurance manual.

Figure 5 shows the QA organization as described above. The particular functions of each position (relative to QA) shown in the diagram and the channels of communication will be delineated in section 5.2.

5.2 FUNCTIONAL RESPONSIBILITIES

The functional responsibility assignments for individuals and organizational components are given in this section.

5.2.1 Accomplishment Plan Manager

A comprehensive QA program includes consideration both of data appropriateness to overall needs and of data quality, in a technical sense. As previously noted, responsibility for planning and documenting a data quality program rests with the taskmaster and within the normal supervisory channels. Evaluation of the relevance of data to broad, long-range HERL-RTP and SPA goals requires a perspective uniquely that of the Accomplishment Plan Manager (APM). Relationships of the research project data to other, spatially and temporally distinct tasks and projects must also be evaluated. Complementarity of purpose between this and other tasks must be weighed. An alert, informed APM can

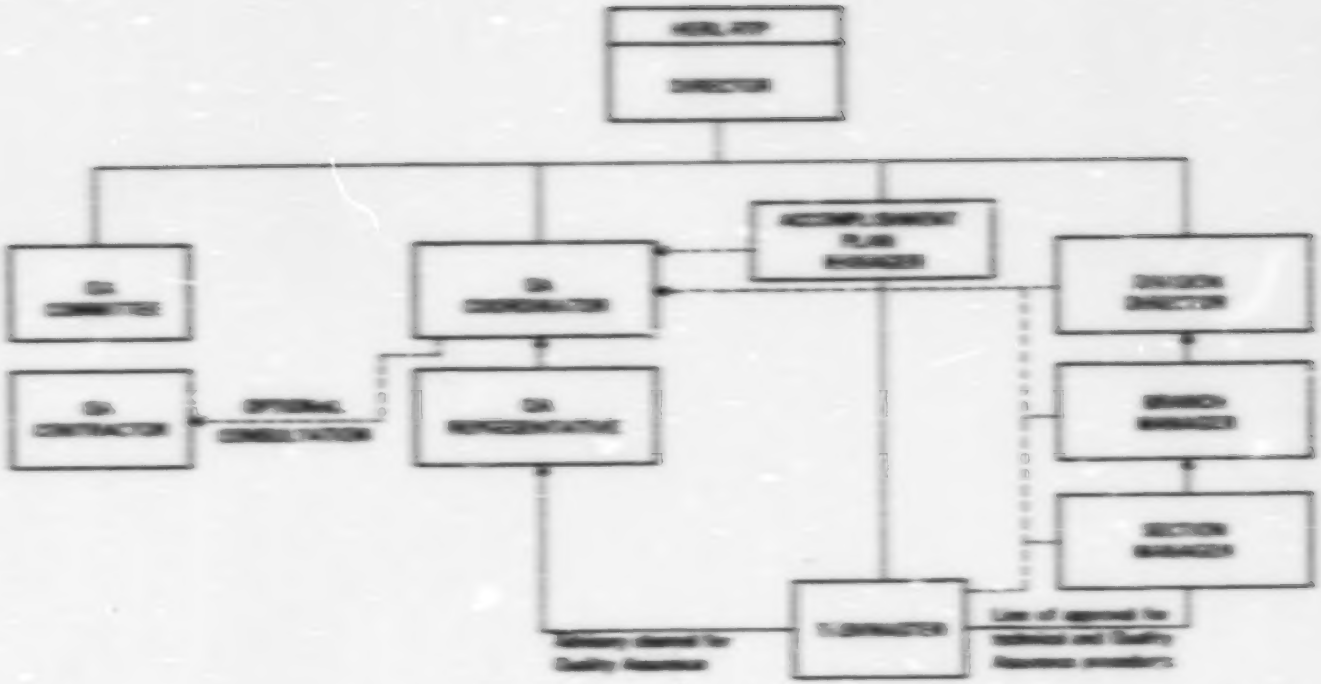

Figure 5. [illegible]

increase the cost-effectiveness of a task by providing responsible insight into possible duplications between tasks, or by recommending additional technical work which would supplement the data from other tasks.

5.2.2 Task Management

The task management is defined here as the project officer or taskmaster who holds the responsibility for fulfillment of the technical and administrative requirements of a task or portion of a task. The task manager's responsibility is to:

a. become acquainted with the technical and administrative requirements of the HERL-RTP quality assurance policy and guideline documents;

b. include QA procedures and criteria with all project documentation (i.e., protocols, RFP's, proposals, workplans, progress reports) and optionally consult with the QA representative from the Division or Office for QA recommendations as specified in the HERL-RTP quality assurance manual (see section 4.3);

c. supply, upon request from the QAC or a designee, QA information and/or data for evaluation by the QAC and/or the QA committee;

d. enlist the assistance of the Division or Office QA representative in the formulation or implementation of QA procedures when necessary; and

e. evaluate the effects of changes in quality assurance definition on project scope, cost, and schedule.

5.2.3 Functional Management

Functional management supervises task management. The responsibilities of the functional managers with respect to the Quality Assurance Program implementation include:

a. reviewing all task documentation for quality control content;

b. soliciting the assistance of the QAC or a designee regarding the QA content of task documents when deemed necessary;

c. insuring that all taskmasters are aware of HERL-RTP's emphasis on maintaining QA performance throughout the task;

d. documenting and submitting a report to the QA representatives on any problem areas in the implementation of the QA program;

e. submitting recommendations for possible improvements in the QA program;

f. working with task management and the QAC or a designee in the application of QA methodologies when necessary;

g. recommending appropriate action when deviations from the QA program plan are identified, in order to maintain high-quality technical performance by functional management; and

h. recommending to the QAC special studies and special test facilities when needed for QA purposes.

5.2.4 Quality Assurance Coordinator

The Quality Assurance Coordinator will administratively function in four capacities, as:

1. coordinator of the HERL-RTP Quality Assurance Program;
2. chief advisor to the Director of HERL-RTP on quality assurance matters;
3. chairman of the Quality Assurance Committee;
4. QA consultant available to all levels of functional and project management.

These four functions are outlined below.

5.2.4.1 As coordinator of the HERL-RTP quality assurance program, the QAC shall:

a. manage the program budget for specific data quality assurance tasks and programs;

b. provide for training of QA representatives in all facets of quality assurance applicable to the projects at hand and those anticipated;

c. identify, categorize, and document changes in QA management philosophies, objectives, acceptable quality criteria, and guidelines;

d. represent the HERL-RTP at Interlaboratory Quality Assurance Coordinating Committee functions within the Environmental Research Center, RTP, and at other QA functions within the agency (see figure 6).

e. become involved with professional societies from which QA expertise can be drawn;

f. recommend more cost-effective methods of quality assurance for evaluation by the QA Committee.

5.2.4.2 The Quality Assurance Coordinator's responsibilities as chief advisor to the HERL-RTP Director on quality assurance matters include:

a. submitting periodic progress reports both in the formulation and implementation stages of the program;

b. enlisting the Director's support when necessary to further the acceptance of the QA program throughout HERL-RTP; and,

c. recommending to the Director major changes in purpose, objectives, or QA management philosophies.

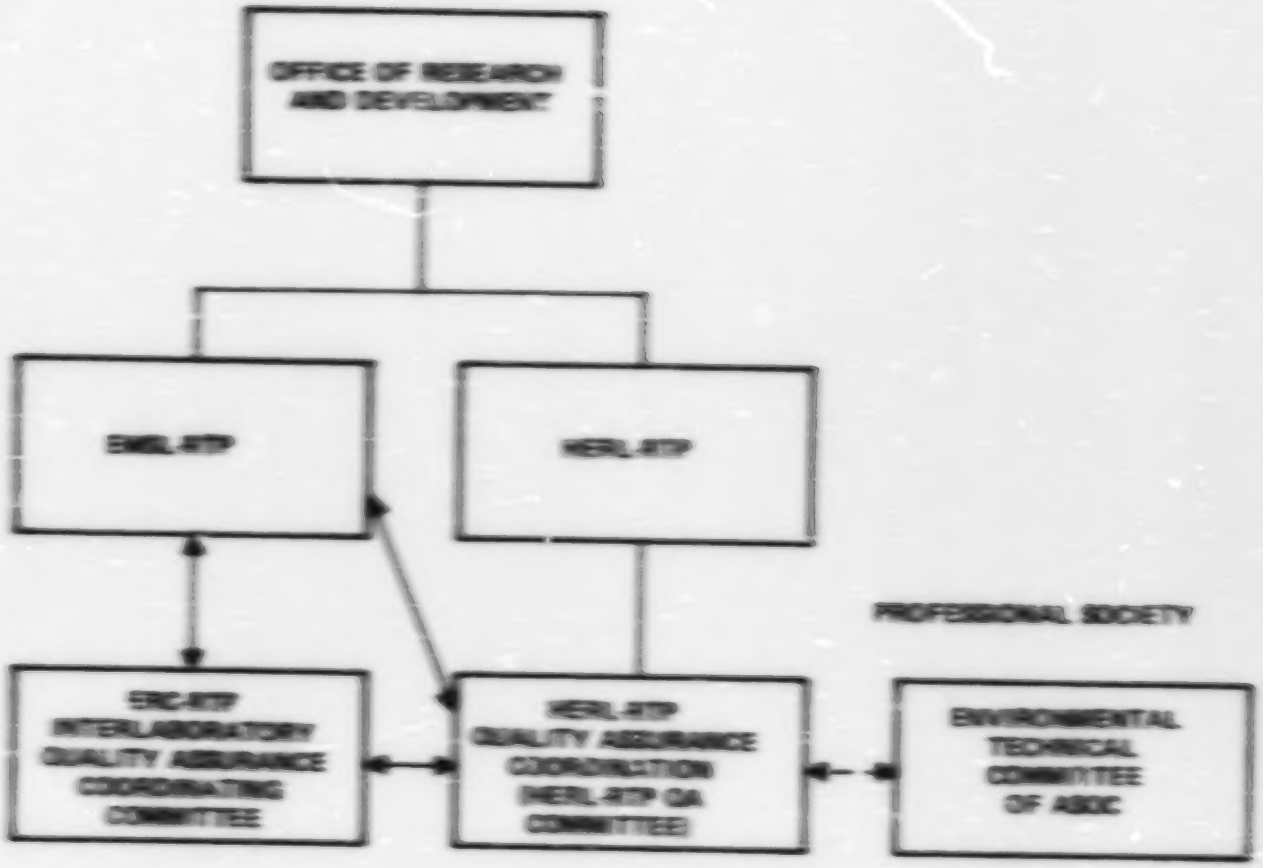

Figure 6. Quality assurance coordinator's communication links with QA expertise outside of EERL-RTP.

5.2.4.3 As chairman of the Quality Assurance Committee, the QAC shall:

a. request sufficient information from the committee members to permit adequate program evaluation;

b. submit new QA methodologies to the committee for discussion and study to determine extent of applicability across HERL-RTP;

c. initiate the committee's efforts in preparing and publishing QA documentation;

d. work with the QA Committee in preparing a master plan for the use of available funds and resources to meet the requirements of the QA directive;

e. work with the QA Committee in planning, organizing, and executing special quality assurance audits of section laboratories' equipment and procedures; and

f. insure that all topics covered and decisions reached in Committee meetings are properly recorded and communicated.

5.2.4.4 As the HERL-RTP Quality Assurance Consultant, the QAC shall:

a. be available for consultation with all levels of functional and project management on QA matters;

b. maintain adequate status information on the quality of project performance so that the taskmaster and functional management have suitable data for evaluation and measurement;

c. provide "real time" feedback on assessments of individual project performances or standard laboratory procedures, following independent QA audits.

5.2.5 Quality Assurance Representative

Each Division or Office Director will designate a Quality Assurance Representative and alternate who will serve as a member of the Quality Assurance Committee as well as the liason between the QA Committee and his or her Division or Office.

As a committee member, the representative shall:

a. study and report to the committee existing or anticipated quality assurance activities within his or her Division or Office;

b. be aware of the scope and quantity of project work performed in-house within the Division or Office;

c. be aware of the scope and quantity of project work contracted out from the Division or Office;

d. identify and report possible problem areas in the implementation of proposed QA activities; and

e. bring to the attention of the QA committee significant suggestions made by functional or project managers within the Division or Office related to quality assurance.

Serving within the Division or Office as the prime source of information on QA matters, the QA representative shall:

a. acquaint functional and task managers within the Division or Office with QA program objectives, policies, and procedures; enlist their support of the program; and project the benefits of a QA program that is incorporated into everyday Division or Office efforts;

b. provide appropriate and timely QA consultation, as necessary;

c. insure that each functional or project manager is supplied with QA documentation applicable to the projects at hand or anticipated; and

d. work with functional and task managers in implementing the QA program within the Division or Office.

5.2.6 Quality Assurance Committee

The Quality Assurance Committee will serve as an advisory committee to the Laboratory Director, with the objective of furthering the continuity and applicability of the Quality Assurance Program throughout HERL-RTP. Specifically, the committee's responsibilities consist of but are not limited to:

a. developing both the short-term and the long-term objectives of the QA Program;

b. periodically assessing program progress and organizational efficiency;

c. assisting in the refinement of the QA Program so that it will meet the needs of all the Division or Offices, with minimum disruption of existing workloads and procedures;

d. reviewing and discussing suggestions and recommendations presented to the committee;

e. reviewing and making recommendations to the QAC as to the definition of QA procedures, and later, assessing the general acceptance and applicability of the QA manual; and

f. formulating, issuing, and maintaining applicable QA documentation.

6. REFERENCES

1. Glossary and Tables for Statistical Quality Control, The American Society for Quality Control, Milwaukee, Wisconsin, 1973.

2. Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I, Principles, EPA-600/9-76-005.

3. Quality Assurance Plan, Health Effects Research Laboratory, Research Triangle Park, North Carolina, 1976 (unpublished).

7. BIBLIOGRAPHY

American Council of Independent Laboratories, Quality Control System for Independent Laboratories, 1971.

Analysis of Pesticide Residues in Human and Environmental Samples, J.F. Thompson, ed., U.S. Environmental Protection Agency, Health Effects Research Laboratory, Research Triangle Park, North Carolina, December 1974.

Army Scientific Advisory Panel, Report of the Army Scientific Advisory Panel Ad Hoc Group on Environmental Quality Control, Washington, NTIS AD-A009-191/8ST, 1975.

Clark, F.E., "Analytical Methodology, Standardization and Quality Control in Environmental Information Systems," ASTM Standardization News, Vol. 4, No. 4 (1976), p. 20-23.

Herbst, R.A., "Contamination Control Management," Quality Progress, Vol. 7, No. 1 (1974), p. 10-17.

Rhodes, R.G., "Quality Assurance For ADP (and Scientific Interaction With ADP)," OAD, EPA Workshop, Proc. No. 2, Nov. 11, 1975.

Rhodes, R.G., and Seymour Hochheiser, "Quality Control Concepts for Environmental Monitoring Systems," American Society for Quality Control Technical Conference Transaction, The Quality Cost System for Air Pollution, Toronto, 1976, not published.

Sherma, Joseph, Manual of Analytical Quality Control for Pesticides and Related Compounds in Human and Environmental Samples, EPA-600/1-76-017, U.S. Environmental Protection Agency, Health Effects Research Laboratory, Research Triangle Park, North Carolina, February 1976.

Shimmin, R.G., Quality Assurance Program, California State Water Resources Control Board, Sacramento, 1974.

Smith, Franklin, and James Buchanan, IERL-RTP Data Quality Manual, EPA-600/5-76-159, U.S. Environmental Protection Agency, Industrial Environmental Research Laboratory, Research Triangle Park, North Carolina, June 1976.

Smith, Franklin, and A. Carl Nelson, Jr., Guidelines for Development of Quality Assurance Programs and Procedures Applicable to Measuring Pollutants for Which National Ambient Air Quality Standards Have Been Promulgated, EPA-Durham 68-02-0598, U.S. Environmental Protection Agency, National Environmental Research Center, Research Triangle Park, North Carolina, August 1973.

Wening, Robert J., "Quality Assurance in the Laboratory," ASTM Standardization News, Vol. 4, No. 3 (March 1976), pp. 11-16.